REMARKS

Claims 1-3, 5-8, and 10-14 are currently pending in this application. The Office Action rejects claims 1-3, 5-8, and 10-14. Applicant respectfully requests reconsideration of the claim rejections for at least the following reasons.

Claims 1-3, 5-8, and 10-14 stand rejected under 35 U.S.C. § 103(a), as being unpatentable over U.S. Patent No. 5,119,801 to Eizenhoefer ("Eizenhoefer") in view of U.S. Patent No. 5,869,189 to Hagood ("Hagood").

To support a *prima facie* case of obviousness, the prior art references must teach or suggest all the claim limitations, or otherwise motivate one of ordinary skill in the art to modify the prior art references to arrive at the claimed invention with some degree of predictability. *See* M.P.E.P. § 2141 *et seq.* Even in light of *KSR International Co. v. Teleflex, Inc.*, a rejection under § 103 must clearly articulate some teaching, suggestion or motivation found in the prior art references or in the common knowledge of a person of ordinary skill in the art to support the proposed combination of references. 550 U.S. 398 (2007). The operative question in the obviousness inquiry is "whether the improvement is more than the predictable use of prior art elements according to their established functions." *Id.* at 417; MPEP § 2141.

Applicant respectfully traverses this rejection on the basis that the Office Action has not established a *prima facie* case of obviousness, because the cited references do not teach or suggest all the claim limitations. Moreover, the cited references do not otherwise motivate or provide predictable guidance to one of ordinary skill in the art to modify the prior art references to arrive at the claimed invention with some degree of predictability.

Independent claim 1 recites an apparatus for generating shock waves comprising (i) piezoelectric fibers integrated in a composite material between (ii) electrical terminals, (iii) a voltage source electrically connected to at least one electrical terminal, and (iv) a coupling membrane defining (v) a volume filled with a shock wave transmission medium between the piezoelectric fibers and the coupling membrane.

The specification explains one of the underlying concepts of the invention is the use of piezoelectric fibers rather than traditional piezoelectric ceramic elements. Specification, p. 4, ll. 2-6. As set forth in the Background section, the use of conventional piezoelectric ceramic elements have several disadvantages in a shock wave device, including: (i) complex and costly production; (ii) high strain of the casting compound caused by deformation of the elements; and (iii) size (miniaturization) limitations. *Id.* at p. 2, ll. 26-36. The present invention is directed to improved, simplified and miniaturized shock-wave generating device, in part by using piezoelectric fibers ("piezofibers"), which were at the time known for use as impact sensors in the aviation industry. *Id.* at p. 4, ll. 10-14. When charged with an external electric field, the piezofibers deform, stretching in their lengthwise direction. *Id.* at p. 4, ll. 18-21. This deformation can be used to generate shock waves. *Id.* at p. 4, ll. 22-23. Preferably, the piezofibers are integrated or embedded in a composite material to form modules which can be utilized in shock-wave generating apparatus. *Id.* at p. 4, ll. 25-29.

In direct contrast to the claimed embodiments, Eizenhoefer teaches piezoelectric shock wave generator that uses traditional piezoelectric ceramic elements. *See* Eizenhoefer, col. 1, ll. 18-21, 29-34. Eizenhoefer seeks to improve upon other conventional devices by providing a structure that insulates and isolates (electrically and mechanically) traditional piezoelectric ceramic elements within the shock wave generating apparatus. *Id.* at co. 1, ll. 36-41. More specifically, the piezoelectric elements are physically separated within the apparatus without any solid or composite material, specifically isolated by a fluid (either liquid or gas) that is disposed in the spaces between the piezoelectric elements. *Id.* at col. 2. l. 66 - col. 3, l. 6 ("that flow space between the piezoelectric element P is filled with insulating liquid I.") and col. 3, ll. 56-59; FIGS. 1-3 (including liquid "I"). Eizenhoefer fails to teach or suggest a shock wave generator that uses piezoelectric fibers in combination with a propagation medium provided between the piezoelectric fibers in a coupling membrane, and fails to teach an apparatus in which such piezoelectric fibers could be integrated or embedded in a solid composite, as recited in pending claim 1.

Hagood is insufficient to cure the aforementioned deficiency of Eizenhoefer. Contrary to the allegation in the Office Action, Hagood is not in the "same field of endeavor" as Eizenhoefer or the present claims—Hagood does not relate to shock wave generating apparatuses, and Hagood explicitly relates only to structural elements for airplanes, automobiles, and the like, without disclosing any medical device application or any predictable guidance for shock wave generation. Without the benefit of hindsight provided in Applicant's own application, one having ordinary skill in the art would not have understood the prospective benefits of combining Hagood's piezofiber composite with the medical application of Eizenhoefer. Therefore, Applicant submits that the combination of Hagood and Eizenhoefer is improper.

Even if Hagood and Eizenhoefer were in the same field of endeavor, Hagood is still insufficient to cure the deficiencies of Eizenhoefer. As discussed in Applicant's previous Response,[1] Hagood fails to teach a shock wave generating apparatus using piezoelectric fibers integrated in a composite, in combination with a propagation medium provided between the piezoelectric fibers in a coupling membrane. As discussed above, Hagood's disclosure is limited to a composite for actuating or sensing deformation of a structural composite (such as for aircraft wings). While Hagood teaches that actuation of the piezofibers can deform the composite material, Hagood does not disclose shock wave generation and does not provide any disclosure to suggest that the mode of deformation of the composite is suitable for shock wave generation in any apparatus, and specifically not in any medical apparatus. In addition, Hagood does not provide any disclosure regarding propagation of shock waves from the composite to a desired treatment focus, such as by combination of the composite with a propagation medium provided between the piezofibers and a coupling membrane. For at least these reasons, Hagood and Eizenhoefer, alone or in combination, fail to teach or suggest all the elements of the shock wave generating apparatus recited in independent claim 1.

[1] Applicant's Response dated Nov. 5, 2008, which is incorporated herein by reference.

Moreover, even if Hagood and Eizenhoefer were in the same field of endeavor Eizenhoefer and Hagood fail to provide any predictable guidance that would lead one having ordinary skill in the art to provide such an apparatus. As mentioned above, the piezoelectric fibers of Hagood in a composite material are used for an established function other than as a shock wave generating apparatus of the present invention. As discussed, Eizenhoefer teaches away from providing a shock wave generator in which the piezoelectric elements are integrated with a solid material such as a composite—instead, Eizenhoefer teaches that it is critical to the effectiveness of the device to use a liquid or gas to separate the piezoelectric elements and not piezoelectric elements in a composite: "Avoidance of that air gap between solid material of the piezoelectric device on one hand and any kind of solid insulation is believed to be the primary agent of effectiveness of invention." Eizenhoefer at col. 1, l. 67 - col. 2, l. 2. Thus, even if Hagood were in a related field of endeavor, one having ordinary skill in the art would expect that providing piezoelectric elements in a Hagood-like composite would not be effective for the purpose of shock wave generation in Eizenhoefer's apparatus, because one would expect gaps to form between the piezoelectric elements and the composite material, causing the loss of electric current.

Unlike Eizenhoefer and Hagood, both individually and in combination, the inventors discovered a way to provide a simplified and miniaturized shock-wave generating device, in part by using piezoelectric fibers embedded or integrated in a composite material. The unique structure of the embodiments provides several advantages not realized by other shock-wave generating devices and for which the cited references provide no predictable guidance. For example, the specification explains that because of the structure of the embodiments, piezofibers may be in contact with an electrically conductive layer, "Hence, the complex interconnection of a multitude of piezoelectric ceramic elements of the known electro-acoustic transducers is no longer required." Specification, p. 4, ll. 36-41. In addition, the unique structure of the embodiments "facilitates a high flexibility" which permits generation of "shock waves of different geometric forms. *Id.* at p.5, ll. 14-17. Furthermore, the structure of the embodiments allows for miniaturization of the shock wave generating apparatus, which

"enables the production of small-sized shock-wave generating apparatuses of the mentioned type for intracorporal applications." *Id.* at p. 5, ll. 35-40. Not only do Eizenhoefer and Hagood fail to teach or suggest the structure of the claimed embodiments, these references also fail to recognize the benefits or any purposes of the invention that may be obtained therefrom. For at least these reasons, Applicant submits that the claimed embodiments are more than just the predictable use of prior art elements according to their established functions. *KSR*, 550 U.S. at 417; MPEP § 2141.

As to dependent claims 2 and 12-14, Eizenhoefer and Hagood, alone or in combination, also fail to disclose a piezoelectric fiber in combination with a shock wave propagation medium and coupling membrane, wherein the piezoelectric fibers are provided lengthwise between respective electrical terminals, as recited in the claims. Furthermore, Hagood fails to disclose at least one electrical connection to the respective terminals of the combination of shock wave producing elements (claim 13) and one electrical connection to the terminals is to an electrically conductive carrier of the combination of shock wave producing elements (claim 14).

As to dependent claims 3, 5-8, 10, and 11, Eizenhoefer and Hagood, alone or in combination, also fail to disclose a carrier coupled to a module of piezoelectric fibers integrated in a composite material, in combination with the other shock wave generating elements, as recited in the claims. Further the references fail to disclose a module with piezoelectric fibers having a common electrical contact in said combination of shock wave producing elements (claim 5); a plurality of modules arranged in said combination of shock wave producing elements (claim 6); a plurality of modules controllable as a group in said combination of shock wave producing elements (claim 7); a plurality of modules interconnected as individually controllable in said combination of shock wave producing elements (claim 8); a carrier in said combination of shock wave producing elements including a geometry selected from the group consisting of planar, spherical and cylindrical (claim 10); and an electrically conductive carrier in said combination of shock wave producing elements (claim 11).

For at least the foregoing reasons, Applicant respectfully submits that claims 1-3, 5-8, and 10-14 are patentable over Eizenhoefer and Hagood, alone or in combination. Therefore, Applicant respectfully requests reconsideration and withdrawal of these claim rejections.

CONCLUSION

Applicant has included a petition and the requisite fee for a three-month extension of time under 37 C.F.R. §1.136. Such additional extension fee should also be charged to Deposit Account No. 50-0206, Order No. 69643.001500. Any overpayment can be credited to Deposit Account No. 50-0206, Order No. 69643.001500. If any additional fees are due in connection with the filing of this Amendment or the accompanying papers, or otherwise in the course of prosecution of this application, please charge the fees to Hunton & Williams Deposit Account No. 50-0206, Order No. 69643.001500.

Respectfully submitted,

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